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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LIMITED, Plaintiffs, v. MYLAN PHARMCEUTICALS INC. and MYLAN INC., Defendants.	Civil Action No. 10-cv-5519 (JAP)(TJB)

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO COMPEL THE MYLAN DEFENDANTS TO PRODUCE RULE 30(b)(6) WITNESS(ES)

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Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited ("AstraZeneca") respectfully submit this memorandum in support of its motion to compel Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Mylan") to produce Rule 30(b)(6) witness(es) for deposition.

PRELIMINARY STATEMENT

This Hatch-Waxman patent infringement litigation concerns AstraZeneca's drug Seroquel XR®, which is approved by the U.S. Food and Drug Administration ("FDA") to treat, *inter alia*, schizophrenia, bipolar disorder and major depressive order as adjunctive treatment with antidepressants. AstraZeneca's U.S. Patent No. 5,948,437 (the "'437 patent"), covers Seroquel XR®'s formulation. Mylan has filed an Abbreviated New Drug Application ("ANDA"), and an amendment thereto, with the FDA seeking approval to market, prior to expiration of the '437 patent, generic versions of Seroquel XR®. Because filing an ANDA constitutes an act of patent infringement under 35 U.S.C. § 271(e)(2)(A), AstraZeneca brought this suit against Mylan for infringement of the '437 patent. Mylan has already conceded that, at least, its proposed 200 mg strength generic sustained release quetiapine product infringes all the claims '437 patent.

BACKGROUND

Mylan filed its original ANDA with a Paragraph IV certification on August 6, 2010. Although Seroquel XR® has five approved strengths, 50, 150, 200, 300 and 400 mg, Mylan's Paragraph IV certification was directed only to the 200 mg strength. On October 14, 2010, Mylan sent AstraZeneca a Notice letter regarding the 200 mg strength and, eight days later, AstraZeneca filed suit. (C.A. No. 10-cv-5519). Mylan filed its Answer on December 10, 2010.

Mylan agreed to be bound by the claim construction entered by the Court. D.I. No. 33; D.I. No. 34.

In view of Mylan's concession of infringement, the parties negotiated an appropriate scope of fact discovery. Among other discovery requests, AstraZeneca served a limited Rule 30(b)(6) deposition notice to Mylan on January 7, 2011. Exh. 1. Mylan never served a formal response to the Rule 30(b)(6) notice and confirmed several times in late March that it would be providing Rule 30(b)(6) witnesses soon. *See* Exh. 2 (3/24/11 Letter from Jaros to McGraw; "[W]e will be in touch with a … date for Mylan's 30(b)(6) designees); Exh. 3 (3/25/11 email from Jaros to McGraw; "[W]e expect to provide dates for the Rule 30(b)(6) deposition next week, and we anticipate [that] the deposition will proceed in Southpointe [Pennsylvania] or Morgantown [West Virginia].")

Mylan advised that they would offer deposition dates in late April or early May. Exh. 3 ("If AstraZeneca is unavailable to take Mylan's deposition on the following dates, let us know: Apr 19; May 5, 6, [and] 13."). AstraZeneca wrote back, requesting Mylan to provide additional dates in April because AstraZeneca did "not want to wait until May to take these depositions." Exh. 4 (3/28/11 Letter from McGraw to Jaros). Mylan never responded. AstraZeneca wrote to Mylan a few weeks later reminding it of its agreement to provide witnesses, and demanding that it provide dates immediately. Exh. 5 (4/15/11 email from McGraw to Jaros). Mylan still did not respond.

AstraZeneca wrote again, demanding that Mylan provide witness dates or "let us know your availability for a meet and confer so that we can seek any necessary court assistance." Exh. 6 (4/28/11 email from McGraw to Jaros). Mylan wrote back to say that they "had not had a chance to consider your email," but would "respond to your email more fully next week." Exh. 7 (4/29/11 email from Shannon to McGraw). Mylan did not respond that next week.

On April 21, 2011, Mylan sent a second Paragraph IV certification, notifying AstraZeneca that it amended its ANDA for the remaining dosage strengths (50 mg, 150 mg, 300 mg and 400 mg) not included in its original ANDA. AstraZeneca sued Mylan again on April 29, 2011 asserting infringement of the '437 patent by the additional dosage strengths in Mylan's amended ANDA. (C.A. No. 11-cv-2483).

On or about May 10, 2011, Mylan's counsel left a phone message for AstraZeneca's counsel on "a couple of issues." However, Mylan's counsel made no attempt to schedule a call or meet-and-confer. On May 16, 2011, six weeks after Mylan agreed to provide witnesses, AstraZeneca made its final demand for a witness. Exh. 9 (5/16/11 email from McGraw to Shannon).

Mylan finally consented to a meet-and-confer by telephone on May 18. During that call, Mylan reversed its prior position and, for the first time, refused to provide a Rule 30(b)(6) witness, concocting a vague "due process concern" relating to the *second-filed* action. In an effort to avoid providing this relevant discovery, Mylan offered to agree to consolidation of the first and second-filed cases if AstraZeneca would withdraw its Rule 30(b)(6) notice. Alternatively, Mylan's counsel stated that if the cases were not consolidated "it would provide Rule 30(b)(6) witness(es) but only if AstraZeneca agrees that such deposition(s) would occur once and be applicable to both Mylan cases." Exh. 10 (5/18/11 email from Renk to Jaros). AstraZeneca could not accept Mylan's offer because there should not be two trials for products under the same ANDA.

AstraZeneca rejected Mylan's proposal and, therefore, now moves to compel the production of Rule 30(b)(6) witnesses.

ARGUMENT

Mylan cannot legitimately refuse to produce corporate witness(es) pursuant to Rule 30(b)(6). Indeed, Mylan *already* agreed to provide a witness and then improperly withdrew its agreement.

Pursuant to Fed. R. Civ P. 30(b)(6), a party may name the deponent as a public or private corporation, and it may set out the matters on which each person designated will testify. The named organization must then designate one or more officers, directors, or managing agents to testify on their behalf. *See Munich v. American National Insurance*, 2011 WL 1466369, at *12-13 (D.N.J. 2011). The Rule 30(b)(6) notice of deposition places the burden upon the party to "to prepare those persons in order that they can answer fully, completely, unevasively, the questions posed ... as to the relevant subject matters" *Costa v. County of Burlington*, 254 F.R.D. 187, 189 (D.N.J. 2008).

Mylan has never objected to the form or substance of AstraZeneca's Rule 30(b)(6) Notice. Mylan does not deny that it is obligated to produce appropriate corporate witnesses in response to AstraZeneca's Rule 30(b)(6) deposition Notice. Mylan never objected to, or otherwise contested, the scope of the deposition notice. Mylan made no objections based on over breadth, undue burden, or relevancy. Indeed, Mylan did not formally reply to Plaintiffs' Rule 30(b)(6) Notice *at all*.

Additionally, any such objections would be futile because this Court already resolved the issues surrounding the same Rule 30(b)(6) Notice to other defendants. *See* Exh. 11 (1/20/11 Letter from Flaherty to Magistrate Judge Bongiovanni). The testimony AstraZeneca seeks is relevant to at least secondary considerations of nonobviousness. AstraZeneca fully explained the deposition topics' relevancy in its January 20, 2011 letter motion to compel other defendants to produce witnesses on virtually identical topics. For example, as AstraZeneca explained then, "Through Topics 1-8, AstraZeneca seeks testimony on the full scope of each

defendant's sustained-release quetiapine formulation development. Each of these topics could produce evidence of things such as copying, failure of others, long-felt need, praise for the invention of the patent, etc." Exh. 11. This Court's February 4, 2011 Letter Order held that AstraZeneca's Rule 30(b)(6) Topics are proper and ordered the Rule 30(b)(6) depositions to go forward for the order defendants. Exh. 12 (2/4/11 Letter Order). AstraZeneca seeks the same scope of deposition testimony from Mylan that the court previously ordered from the other defendants.

Mylan's reasons for reneging on its agreement to produce a corporate witness(es) are not clear. Mylan never explained why it no longer will produce witnesses other than "due process" concerns. Apparently, Mylan contends that due process concerns related to its amended ANDA and the second complaint relieve it of its obligation. Mylan raised this argument for the first time at the May 18 meet-and-confer, but offered no cases or other legal authority in support.

The requested discovery is both relevant and timely. Mylan has not objected, with the exception of its new due process claim. Yet the cases are now consolidated, and trial is scheduled. AstraZeneca cannot stand by and let Mylan simply refuse to produce Rule 30(b)(6) deposition witnesses to testify on relevant topics. This discovery should be compelled.

CONCLUSION

AstraZeneca respectfully submits, under these circumstances, that an order compelling Mylan to produce Rule 30(b)(6) witness(es) be granted.

Respectfully submitted,

Dated: May 27, 2011

By: /s/ John E. Flaherty

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